In the Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-414

HYNSON, WESTCOTT & DUNNING, INCORPORATED,
CROSS-PETITIONER

v.

ELLIOT RICHARDSON, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

MEMORANDUM FOR THE RESPONDENTS

In *Richardson* v. *Hynson, Westcott & Dunning, Inc.*, No. 72-394, the government has petitioned for a writ of certiorari to review the decision of the court of appeals in this case that the Food and Drug Administration (FDA) was required to give Hynson, Westcott & Dunning ("Hynson") an evidentiary hearing prior to withdrawing approval of its New Drug Application (NDA) for the marketing of its drug product, Lutrexin, for failure to meet the efficacy requirements of the 1962 amendments to the Federal Food,

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Drug, and Cosmetic Act of 1938. That petition raises an important question regarding the ability of the agency, without being required to hold evidentiary hearings, to withdraw marketing authority for numerous drugs for which no prima facie showing of effectiveness in accordance with the statutory standard of "substantial evidence" can be made.

The cross-petition raises threshold questions relating to the applicability of the drug efficacy and "substantial evidence" requirements to Lutrexin. These threshold questions are not peculiar to Lutrexin, but are bound to arise in connection with numerous other drugs that are potentially subject to withdrawal of NDA's under the efficacy requirements of the 1962 amendments. We believe that these issues are fairly raised by this case and that their resolution by this Court is important to the administration of the Federal Food, Drug, and Cosmetic Act of 1938, as amended. Accordingly, we agree that the Court should grant certiorari on the issues raised by the cross-petition, although, as indicated briefly below, we believe that Hynson's view of the proper resolution of these issues is erroneous, that Lutrexin is subject to the efficacy and "substantial evidence" requirements of the Act, and that there were no factual issues requiring resolution in an evidentiary hearing prior to withdrawal of Lutrexin's NDA.

1. Throughout the proceedings below, Hynson has contended that Lutrexin is not subject to the efficacy requirements of the 1962 amendments because it was generally recognized as safe at the time those amend-

ments went into effect and was therefore entitled to the exemption granted by Section 107(c)(4) from the efficacy requirements. Question 4 in the cross-petition (Pet. 3, 14–17) presents this issue. The court of appeals rejected this contention, concluding that since the NDA for Lutrexin, which was granted in 1953, had never been withdrawn, the drug was "covered by an effective application" within the meaning of Section 107(c)(4)(C) and therefore ineligible for the exemption (Pet. App. 23a–24a).[1] We agree with that holding. Indeed, Hynson's view that general recognition of safety by 1962 provides exemption would render clause (C) (set forth at Pet. App. 9a) meaningless and redundant. That clause has meaning only if, as the court below held, NDA's are "effective," for purposes of the statute, unless withdrawn, irrespective of any general recognition of the drug's safety that may have come about between the time of the NDA's effectiveness and the effective date of the 1962 amendments.

If this Court were to agree with Hynson's view of this issue, it would then be necessary, in administering the 1962 amendments, to determine the applicability of the efficacy requirements in the first instance by inquiring into a drug product's recognition for safety as of 1962, which would entail a major change from NDA withdrawal procedures now being pursued.

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[1] In reaching this conclusion, the court of appeals cited its decision in *USV Pharmaceutical Corp.* v. *Richardson* (Pet. App. 45a–54a), in which it discussed this issue at somewhat greater length. USV has petitioned for a writ of certiorari to review that decision (No. 72–666).

Additionally, the question is important because, should Hynson's view prevail, the impact of the efficacy requirements, as applied to drugs for which NDA's were filed prior to 1962, would be seriously constricted; thus, the issue is fundamental to establishing the reach of the 1962 amendments.

2. Question 3 presented by the cross-petition (Pet. 3, 17–20) raises a closely related legal question regarding the power of FDA to withdraw approval of an NDA in light of Section 107(c)(2). Relying upon the same basic contention that the NDA ceased to be "effective" when the drug achieved general recognition of safety, Hynson argues that the NDA for such a drug should not be "deemed * * * to be an application 'approved' by the Secretary * * *" and should therefore not be subject to administrative withdrawal of NDA approval under the efficacy requirements of Section 505(e)(3) (see Pet. 17–18). The factual issue presented, if Hynson's reading of the statute is correct, is identical to that presented under Hynson's interpretation of Section 107(c)(4), discussed above—was the drug generally recognized as safe at the time the 1962 amendments went into effect? The impact of a resolution of this question favorable to Hynson would also be similar, both in terms of the effective reach of the 1962 amendments and in terms of the manner of their administration.[2]

[2] It is true, as Hynson concedes, that the argument predicated on Section 107(c)(2), in contrast to that based on 107(c)(4), would not wholly eliminate the Act's efficacy requirements—it would eliminate effective administrative remedies but would leave the possibility of recourse to judicial remedies. As a

In our view, Hynson's strained interpretation of Section 107(c)(2) is incorrect. The obvious purpose of that provision was quite simple. Congress declared in that provision that previously issued NDA's were "deemed approved" because the 1962 amendments had changed the procedure whereby NDA's became operative. Prior to 1962, applications automatically became effective after the passage of a period of time following their filing, unless disapproved; thus, no formal approval was ever issued. The 1962 amendments, however, imposed an affirmative requirement of approval. Since previous NDA's had not been administratively "approved" but had simply become "effective" automatically, it was necessary for Congress to provide that all NDA's "effective" on the date of the amendments were deemed "approved" in order to make it clear that they were subject to the new "effectiveness" standards of the Act. Thus, far from insulating drugs for which NDA's had been filed under the old safety criteria, Section 107(c)(2) evidences the intent of Congress to insure that such drugs would be subject to the "effectiveness" requirement.

3. Question 2 presented by the cross-petition (Pet. 3, 13-14) apparently is intended to raise another related, and also important, issue. This is Hynson's con-

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practical matter, however, the effect would be nearly the same, since FDA does not have the resources to pursue judicial relief against the hundreds of drugs that might fall in the category claimed for Lutrexin of insulation from NDA withdrawal proceedings. Moreover, it is not clear whether "substantial evidence" of effectiveness—the statutory criterion for NDA withdrawals—would be required in defense against a seizure action or other judicial remedy.

tention that it should be entitled to show, at the time FDA is considering withdrawal of a previously issued NDA, that the agency is without jurisdiction to act because the drug has ceased to be a new drug, having become generally recognized as both safe and effective (the criteria under the amended Act). This argument (which was not discussed by the court of appeals) is, in essence, an attempt to avoid the impact of the "substantial evidence" requirement adopted by Congress in Sections 505 (d) and (e) of the Act (Pet. App. 3a-6a) as the standard for determinations of efficacy. In other words, Hynson seeks to be able to rely on the kind of evidence it submitted to FDA to establish "general recognition" of efficacy, thereby, in its view, depriving the agency of the power to move against its drug even though there is no "substantial evidence" of efficacy.

Almost any drug that has been on the market since 1962 or earlier, and that has been sufficiently successful economically that the manufacturer desires to resist its removal from the market for ineffectiveness, is likely to have some sort of "recognition" of safety and effectiveness among some members of the medical profession. The manufacturer of such a product, therefore, could produce testimonials in its support sufficient, under Hynson's contention, to raise an issue requiring a hearing even in the absence of any evidence of the kind defined by Congress as "substantial evidence." The result of acceptance of Hynson's position on this issue thus would be effectively to read

the "substantial evidence" requirement out of the statute, at least with respect to withdrawals, and to allow manufacturers having no "adequate and well controlled investigations" substantiating the effectiveness of their products to avoid the NDA procedure. We do not agree that the clear intent of Congress can be so readily subverted; in our view, there can be no general recognition of safety and effectiveness in the absence of "substantial evidence" of effectiveness.

4. Question 1 presented by the cross-petition (Pet. 3, 9–12) concerns the jurisdiction of FDA to determine whether Lutrexin is exempt from withdrawal of its NDA under any of the threshold jurisdictional contentions presented by questions 2 through 4 of the cross-petition. In other words, if this Court should agree with Hynson on its claims that it is entitled as a matter of law to prove that Lutrexin is exempt from the Act because generally recognized as safe at the time the 1962 amendments went into effect (questions 3 and 4 of the cross-petition) or because generally recognized as safe and effective today (question 2), the Court would also have to determine whether, on remand, the agency has the jurisdiction to resolve the factual questions upon which the availability of any such exemption rests.

Under the ruling of the court of appeals in *Bentex Pharmaceuticals, Inc.* v. *Richardson* (Pet. App. 29a–44a), the agency apparently would not have such jurisdiction, and the questions would have to be resolved in the district court. The government has peti-

tioned for a writ of certiorari to review the *Bentex* decision (No. 72-555), and we agree with Hynson that the agency should and does have jurisdiction to determine such questions. (Of course, we do not agree that any such jurisdictional questions are present in the case of Lutrexin, since, as indicated above, we believe that the contentions advanced by Hynson in its cross-petition as grounds for exemption from the Act's efficacy requirement are lacking in legal merit.)

5. The questions presented in the cross-petition reflect recurring contentions made by manufacturers seeking to avoid application of the efficacy requirements of the 1962 amendments (and the "substantial evidence" standard embodied therein) to their products. In order to avoid fragmented litigation of these questions in federal courts all over the country during the next several years, we believe it is important for this Court to provide an authoritative interpretation of the efficacy provisions contained in the 1962 amendments. This case, together with *Bentex*,[3] provides a suitable framework for resolution of these complex, important, and interrelated problems.

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[3] Similar issues are also presented in two additional cases now pending on petitions for writs of certiorari. *Ciba Corporation* v. *Richardson*, No. 72-528; *USV Pharmaceutical Corp.* v. *Richardson*, No. 72-666.

CONCLUSION

For the reasons stated, the cross-petition for a writ of certiorari, as well as the government's petition, should be granted.

Respectfully submitted.

ERWIN N. GRISWOLD,
Solicitor General.

THOMAS E. KAUPER,
Assistant Attorney General.
PETER BARTON HUTT,

PETER BARTON HUTT,
Assistant General Counsel,
Food, Drugs, and Product Safety Division,
Department of Health, Education, and Welfare.

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